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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/531,347	02/27/2006	Jost Scibler	100725-47 (KGB)	3093
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EXAMINER NOBLE, MARCIA STEPHENS				
ART UNIT		PAPER NUMBER		
1632				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/531,347

Applicant(s)

SEIBLER ET AL.

Examiner

MARCIA S. NOBLE

Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14-44 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 14-44 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/55/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date ____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: ____.

DETAILED ACTION

1. Claims 14-44 are pending.

Preliminary Matters

2. All of the dependent claims of the instant claims set depend from cancelled claims. The restriction has been crafted based upon assumed relationships between the independent claims and dependent claims. Applicant is required to amend the claims to place them in proper dependent formation. Applicant is reminded that upon such amendments the groupings of the invention are subject to change.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 14-16, 18-40, and 44, drawn to an in vitro method of gene knock down in vertebrate cells, more specifically in a mouse tissue or cell culture comprising stably integrating an expression vector comprising a short hairpin RNA construct under the control of a ubiquitous promoter into the genome of a mouse cell.

Group II, claim(s) 14-40 and 44, drawn to an in vivo method of gene knock down in a vertebrate, more specifically a mouse, comprising stably integrating an expression vector comprising a short hairpin RNA construct under the control of a ubiquitous promoter into the genome of a mouse cell.

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Group III, claim(s) 14-16, 18-40, and 44, drawn to an in vitro method of gene knock down in a vertebrate cells, more specifically in a fish tissue or cell culture comprising stably integrating an expression vector comprising a short hairpin RNA construct under the control of a ubiquitous promoter into the genome of a fish cell.

Group IV, claim(s) 14-40 and 44, drawn to an in vivo method of gene knock down in a vertebrate, more specifically a fish, comprising stably integrating an expression vector comprising a short hairpin RNA construct under the control of a ubiquitous promoter into the genome of a fish cell.

Group V, claim(s) 41-44, drawn to a transgenic vertebrate, more specifically a mouse or cell cultures therefrom comprising an expression vector comprising a short hairpin RNA construct under control of a ubiquitous promoter, stably integrated into its genome, preferably at a polymerase II dependent locus of the mouse.

Group VI, claim(s) 41-44, drawn to a transgenic vertebrate, more specifically fish or cell cultures therefrom comprising an expression vector comprising a short hairpin RNA construct under control of a ubiquitous promoter, stably integrated into its genome, preferably at a polymerase II dependent locus of the fish.

The inventions listed as Groups I-VI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

A) The invention has no special technical feature that defined the contribution over the prior art, or

B) Unity of invention between different categories of inventions will only be found to exist if specific combinations of inventions are present. Those combinations include:

- 1) A product and a special process of manufacture of said product.
- 2) A product and a process of use of said product.
- 3) A product, a special process of manufacture of said product, and a process of use of said product.
- 4) A process and an apparatus specially designed to carry out said process.
- 5) A product, a special process of manufacture of said product, and an apparatus specially designed to carry out said process.

The allowed combinations do not include multiple products, multiple methods of using said products, and methods of making multiple products as claimed in the instant application, see MPEP § 1850.

Applicant's claims encompass multiple inventions and do not have a special technical feature which link the inventions one to the other, and lack unity of invention.

A) The invention has no special technical feature that defines the contribution over the prior art because Paddington et al (Genes & Dev 16:948-958, April 2002).

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Claim 1 is drawn to a method for constitutive and/or inducible gene knock down in a vertebrate, or in a tissue culture or cells of a cell culture derived from a vertebrate, which method comprises stably integrating an expression vector comprising a short hairpin RNA construct under control of a ubiquitous promoter into the genome of the vertebrate, of the tissue culture or of the cells of the cell culture.

Paddington discloses a method of stably transfecting mammalian cells with a plasmid encoding a short hairpin RNA (p. 957, col 1, par 1). Paddington discloses an the transfected expression vector comprised the ubiquitous H6 promoter and short hairpin RNA to the p53 gene (p. 957, col 1, last par). Paddington discloses that the short hairpin RNA expression silences p53 expression in mammalian MEF cells in culture (p. 956, Figure 6). Therefore, because Paddington discloses the invention of claim 1, the instant invention has no special technical feature that defines a contribution over the prior art. Therefore, the invention lacks unity.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

a) CMV promoter, CAGGS promoter, a snRNA promoter, a RNase P RNA promoter, a tRNA promoter, a 7SL RNA promoter, a 5 S rRNA promoter, tet, Gal4, and lac promoter

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include

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all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner:

a) a constitutive or inducible promoter

The following claim(s) are generic: 21-28.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: inducible and constitutive promoters were both known in the prior art as taught by Paddington above and therefore lack the same special technical features.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01. Any inquiry concerning this communication or earlier communications from the examiner should be

directed to MARCIA S. NOBLE whose telephone number is (571)272-5545. The examiner can normally be reached on M-F 9 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on (571) 272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Marcia S. Noble

/Peter Paras, Jr./
Peter Paras, Jr.
Supervisory Patent Examiner, Art Unit 1632